MAY 12 2006

SECTION 5
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4178
Fax: 508-683-5939

Contact: Jennifer A. Kimball, RAC
Principal Regulatory Affairs Specialist
Date Prepared: February 8, 2006

2. Device:

Trade Name: Ultraflex™ Precision™ Colonic Stent System
Common Name: Expandable, metallic colonic stent
Classification Name: Stent, colonic, metallic, expandable
Regulation Number: 878.3610
Product Code: MQR
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's Ultraflex™ Precision™ Colonic Stent System, K030769
Boston Scientific Corporation's Wallstent Enteral Stent, K000281
Both predicates are class II devices per 21 CFR 878.3610

4. Device Description:

The proposed Ultraflex™ Precision™ Colonic Stent System consists of a self-expanding metal stent and a delivery catheter. The proposed stent consists of Nitinol wires wound together to form a cylinder with a flared distal section. The proposed stent is mounted on a delivery catheter. The stent is compressed onto the tapered delivery catheter shaft and bound with braided nylon suture using a crochet stitch. The stent is deployed by holding the handle stationary and pulling a ring to unravel the crochet stitch.

5. Intended Use:

The Ultraflex™ Precision™ Colonic Stent is indicated for palliative treatment of colonic strictures in the descending colon, sigmoid colon and rectum caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

6. Technological Characteristics:

The proposed Ultraflex Precision Colonic Stent has the identical technological characteristics (materials, construction, manufacturing processes) as the currently marketed Ultraflex Precision Colonic Stent.

7. Performance Data:

As this is a request for an additional indication and introduces no new materials or design changes the performance testing presented in K030769 was not repeated. Clinical data in support of the proposed indication has been collected and is presented within this submission.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Ultraflex™ Precision™ Colonic Stent is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex™ Precision™ Colonic Stent and, in terms of the proposed indication to Boston Scientific Corporation's Wallstent Enteral Stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 12 2006

Ms. Jennifer Kimball
Principal Regulatory Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K060323
Trade/Device Name: Ultraflex™ Precision™ Colonic Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MQR
Dated: February 8, 2006
Received: February 13, 2006

Dear Ms. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K060323

SECTION 4
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): ~~**To Be Determined**~~ K060323

Device Name: **Ultraflex™ Precision™ Colonic Stent System**

Indications For Use:

The Ultraflex™ Precision™ Colonic Stent is indicated for palliative treatment of colonic strictures in the descending colon, sigmoid colon and rectum caused by malignant neoplasms and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

Prescription Use ___X___ AND/~~OR~~ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060323